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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,231	12/29/2000	Richard N. Ellson	7610-0040	8767

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/02/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,231

Applicant(s)

ELLSON ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-58 and 81-84 is/are pending in the application.
- 4a) Of the above claim(s) 11-18,50-53,55,57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 19-48, 54, 56, and 81-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/03 has been entered.

Status of Claims

2. Applicant's amendment filed 7/28/03 in Paper No. 13 is acknowledged and entered. Claims 1, 3, 54, 56 are amended by the amendment. Claims 81-84 are added by the amendment.
3. Claims 2, and 59-80 are cancelled by amendment filed 3/3/2003.
4. Claims 11-18, 55, 57, and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a *nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.
5. Claims 50-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a *nonelected invention*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

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6. Claims 1, 3-58, and 81-84 are pending.
7. Claims 1, 3-10, 19-49, 54, 56 and 81-84 are treated on the merit in this Office Action.

Drawings

8. The drawings were received on 9/31/03. These drawings are acceptable.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3-10, 19-49, 54, 56 and 81-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The presently claimed device briefly recites a device comprising a plurality of different molecular probes attached to a surface and an integrated indicator, wherein the integrated indicator exhibits a detectable response when the device is exposed to a condition and removed from the condition.

The recitation of ‘the device is exposed to a condition and removed from the condition.’ claimed in claims 1, 3, 54, and 56, have no clear support in the specification and the claims as originally filed. The specification in page 13 disclosed *‘the indicator response to the condition is*

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detectable for at least 1 minute after removing the indicator from the condition' (line 6) is not support for *'the device is exposed to a condition and removed from the condition'*. Because the narrow limitation of the specification recites that the indicator is exposed to and removed from the condition, it does not support the broad limitation of the claim, which recites the device is exposed to a condition and removed from the condition. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of device is exposed to a condition and removed from the condition.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

11. Claims 1, 3-10, 19-49, 54, 56 and 81-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection).

The instant invention of claim 1 is directed to a device comprising a plurality of different molecular probes attached to a surface and an integrated indicator, wherein the integrated indicator exhibits a detectable response when the device is exposed to a condition and removed from the condition. There is no claimed structure or other identifying characteristics presented with respect to the type of "probe" (e.g. the specific type of probe such as DNA or protein) and "integrated indicator" (e.g. the specific type of indicator such as fluorescence label) or for that matter the relationship between the probe, and indicator (e.g. does the indicator produce a signal

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when the probe interact with the target such as DNA-protein interaction or the indicator is synonymous to the target with a label) and how the “detectable response” of the indicator is detected (e.g. the type of detector). Additionally, the type of “condition” claimed to which the device is exposed would depend on the type of probe-target interaction (e.g. DNA hybridization or antigen-antibody interaction).

The specification description is directed to an indicator that are labeled probe (e.g. labeled DNA strand (pg. 21, lines 16-27), fluorescence probe (pg. 24, lines 2-12) and condition of DNA hybridization (pg. 28, lines 2-10), which clearly do not provide an adequate representation regarding the open ended claimed the “probe”, or “integrated indicator” (e.g. other type of probe such as protein or other type of indicator such as luminescence label) and the “condition” specific for other type of probe-target interaction (e.g. antigen-antibody interaction) for the device of the presently claimed invention.

With regard to the description requirement, Applicants’ attention is directed to The Court of Appeals for the Federal Circuit which held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to any compound; which requires a representative sample of compounds and/or a showing of

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sufficient identifying characteristics; to demonstrate possession of the claimed generic(s) (e.g. all type of “probe”, “integrated indicator”, or assay “condition”).

In the present instance, the claimed invention contains no identifying characteristics regarding the “probe” and “integrated indicator”.

Additionally, the narrow scope of examples directed to an indicator that are labeled probe (e.g. labeled DNA strand (pg. 21, lines 16-27), fluorescence probe (pg. 24, lines 2-12) and condition of DNA hybridization (pg. 28, lines 2-10) is clearly not representative of the scope of detecting all type of proteins with any type of “probe”, “integrated indicator”, or assay “condition” of the presently claimed invention.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 3-10, 19-49, 54, 56 and 81-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term “predetermine temperature” of claim 6 is a relative term, which renders the claim indefinite. The term “predetermine temperature” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

b. The term “maximum” of claim 7 is a relative term, which renders the claim indefinite. The term “maximum” is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

c. The term “minimum” of claim 9 is a relative term, which renders the claim indefinite. The term “minimum” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

d. The term “predetermine period” of claim 24 is a relative term, which renders the claim indefinite. The term “predetermine period” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

e. Claims 81 and 84 recites the limitation "indicator structure" in line 1. There is insufficient antecedent basis for this limitation in claim 6 for which it depends.

f. Claim 81 is rejected to under 37 CFR 1.75 as being a substantial duplicate of claim 49. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1-10, 19-33, 38-49, 54, 56, and 81-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Nova et al. (US Patent 5,874,214).

Nova et al. disclose a device that is combination of matrix materials with programmable data storage or recording devices (col. 4, lines 55-64). The matrices are generally insoluble materials used to immobilize ligands and other molecules (molecular probes) (col. 18, lines 33-39). The recording and storage device is in proximity with or in contact with the matrix (col. 5, lines 44-46). The recording device can detect the occurrence of a reaction and record the event in the memory (integrated indicators)(col. 37, lines 31-33). The sensor in the recording device would include a temperature sensor to record the temperature of the reaction (col. 38, lines 47-63; col. 49, lines 55-63; col. 53, lines 44-50) (referring to claims 5-6). Other type of sensors can be use in the combination of matrix materials with programmable data storage or recording devices such as a photodetector to detect the occurrence of fluorescence or other optical emission

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(col. 6, lines 25-27) (referring to claims 19-23), or electromagnetic tagging (col. 14, lines 49-57) (referring to claims 19-23, 49, and 81-84). The composition of matrices with memories and molecules would include biological particles such as oligonucleotides, peptides, proteins, and cells (col. 10, lines 1-6) (referring to claims 28-32). The matrix would be in the form of a continuous surface such as a microtitre dish, or a glass slide (col. 12, lines 60-63) (referring to claims 33 and 43-46).

Response to Arguments

16. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Nova et al. (US Patent 5,874,214) for claims 1-10, 19-33, 38-49, 54, 56, and 81-84 were considered but they are not persuasive for the following reasons.

Applicant argues that the functional limitation of the device in that “[t]he indicator continues to exhibit the response for at least one minute after the device is removed from the condition” differentiate the presently claimed device from that of Nova et al. Thus the device of Nova et al. does not anticipate the presently claimed device. Applicant’s arguments are not convincing since the functional limitation is a recitation of an intended operation of a claimed apparatus (e.g. the manner of operating the device) that would not differentiate the device from the Nova et al. since the device of Nova et al. meets all the structural limitation of the presently claimed device (e.g. a probe attached to the surface and an integrated indicator).

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

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Additionally, the limitation of claim 49, and 81-84 wherein the “structure of the indicator” is a labeled DNA probe encompassed the indicator of Nova et al. (col. 14, lines 49-57). Thus, the device of Nova et al. does anticipate the presently claimed device.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., structures having a prolonged or permanent response are preferred over a transient or quickly reversible response) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

17. Claims 1, 43, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (US Patent 6,342,349 B1).

Virtanen disclose a device comprise of an optical disk having a plurality of analyte-specific signal elements that is cleavable and the signal is detected from the cleave signal element (col. 7, lines 29-35). The cleavable signal element comprises a signal responsive moiety (indicator) attached to the cleavable spacer at its signal responsive end (probe) (col. 5, lines 30-36). The cleavable spacer has a substrate-attaching end. The device of Virtanen anticipates the presently claimed invention.

Response to Arguments

18. Applicant's argument(s) directed to the above rejection under 35 USC 102(e) as being anticipated by Virtanen (US Patent 6,342,349 B1) for claims 1, 43, and 56 was(were) considered but they are not persuasive for the following reasons.

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Applicant alleges that the functional limitation of the device in that “[t]he indicator continues to exhibit the response for at least one minute after the device is removed from the condition” differentiate the presently claimed device from that of Virtanen. Thus the device of Virtanen. does not anticipate the presently claimed device. Applicant’s arguments are not convincing since the functional limitation is a recitation of an intended operation of a claimed apparatus (e.g. the manner of operating the device) would not differentiate the device from the Virtanen since the device of Virtanen meets all the structural limitation of the presently claimed device (e.g. a probe attached to the surface and an integrated indicator).

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Additionally, the limitation of claim 49, and 81-84 wherein the “structure of the indicator” is a labeled DNA probe encompassed the indicator of Nova et al. (col. 14, lines 49-57). Thus, the device of Nova et al. does anticipate the presently claimed device.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1, 3-10, 19-49, 54, 56 and 81-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al. (US Patent 5,874,214) and of Wang et al. (US Patent 5,922,617).

Nova et al. disclose a device that is combination of matrix materials with programmable data storage or recording devices (col. 4, lines 55-64). The matrices are generally insoluble materials used to immobilize ligands and other molecules (molecular probes) (col. 18, lines 33-39). The recording and storage device is in proximity with or in contact with the matrix (col. 5, lines 44-46). The recording device can detect the occurrence of a reaction and record the event in the memory (integrated indicators)(col. 37, lines 31-33). The sensor in the recording device would include a temperature sensor to record the temperature of the reaction (col. 38, lines 47-63; col. 49, lines 55-63; col. 53, lines 44-50) (referring to claims 5-6). Other type of sensors can be use in the combination of matrix materials with programmable data storage or recording devices such as a photodetector to detect the occurrence of fluorescence or other optical emission (col. 6, lines 25-27) (referring to claims 19-23), or electromagnetic tagging (col. 14, lines 49-57) (referring to claims 19-23, 49, and 81-84). The composition of matrices with memories and molecules would include biological particles such as oligonucleotides, peptides, proteins, and

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cells (col. 10, lines 1-6) (referring to claims 28-32). The matrix would be in the form of a continuous surface such as a microtitre dish, or a glass slide (col. 12, lines 60-63) (referring to claims 33 and 43-46).

The device of Nova et al. does not expressly disclose that the array comprises of 10, 50,000, 200,000, or 1,000,000 probes on the substrate surface.

Wang et al. disclosed a device in which the microarray would contain 10 or more probes (col. 2, lines 60-65). Wang et al. suggest that the number of individually addressable sites (probes) on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an array of 10 or more probes on the surface of the substrate as taught by Wang et al. for the device of Nova et al. One of ordinary skill in the art would have been motivated to include an array of 10 or more probes on the surface of the substrate in the device of Nova et al. for the advantage of detecting multiple analytes. Since both Nova et al. and Wang et al. disclose a device for detecting multiple analytes (Nova: col. 43, lines 26-28; Wang: col. 2, lines 49-59). Further, Wang et al. suggest that the number of probes on an array would depend on the nature of the bound component, the source of the signal, the nature of the signal being detected, the nature of the bound array such as the size of the microarray or the manner in which it is produced (col. 3, lines 6-11). Therefore, the choice of the number of probe on the surface of the substrate would depend on the availability of bound component and signal used.

Response to Arguments

22. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Nova et al. (US Patent 5,874,214) and of Wang et al. (US Patent 5,922,617) for claims 1, 3-10, 19-49, 54, 56 and 81-84 was(were) considered but they are not persuasive for the following reasons.

Applicant contends that the functional limitation of the device in that “[t]he indicator continues to exhibit the response for at least one minute after the device is removed from the condition” differentiate the presently claimed device from that of Nova et al. Thus the device of Nova et al. and Wang et al. is non-obvious over the presently claimed device. Applicant’s arguments are not convincing since the functional limitation is a recitation of an intended operation of a claimed apparatus (e.g. the manner of operating the device) that would not differentiate the device from the Nova et al. since the device of Nova et al. meets all the structural limitation of the presently claimed device (e.g. a probe attached to the surface and an integrated indicator).

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Additionally, the limitation of claim 49, and 81-84 wherein the “structure of the indicator” is a labeled DNA probe encompassed the indicator of Nova et al. (col. 14, lines 49-57). Thus, the device of Nova et al. and Wang et al. is obvious over the presently claimed device.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

mct
December 1, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER